#### **REMARKS**

Claims 1-26 were examined and reported in the Office Action. Claims 1-4 and 6-26 are rejected. New claims 27-35 are added. Claims 1-26 are amended. Claims 1-35 remain. The amendment to the specification includes example 2, which is contained in the priority document and was inadvertently not included in the filing of the translation. Therefore, no new matter has been added.

Applicant notes that the original claims were drafted in the "Suiss" form and directed to methods for treatment. Since the form of the claims were inadvertently misconstrued, Applicant has amended the claims to more clearly be directed to methods of treatment, so as not to be misconstrued as directed to compositions. Therefore, Applicant submits that a subsequent Office Action not be made final.

Applicant requests reconsideration of the application in view of the following remarks.

#### L Claim Objections

It is asserted in the Office Action that claims 1, 3, 4, 13, 14, 21, 25 and 26 are objected to for use of the abbreviations "PCO" and HSP 32. Applicant has included the non-abbreviated term "Procyanidol Oligmer before the abbreviation PCO. Applicant has also included the non-abbreviated term Heat Shock Protein before the abbreviation HSP.

It is also asserted in the Office Action that claims 4, 6, 8, 10-14, 16, 17, 19-22 and 26 are objected to under 37 CFR 1.75(C) as being in improper form. Applicant has amended the claims to overcome the 37 CFR 1.75(C) objections.

Accordingly, withdrawal of the informal claim objections for claims 1, 3, 4, 6, 8, 10-14, 16-17, 19-22, 25 and 26 are respectfully requested.

# II. 35 U.S.C. §112

It is asserted in the Office Action that claims 1-4 and 6-26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Applicant has amended the claims to overcome the 35 U.S.C. §112, second paragraph rejection.

Accordingly, withdrawal of the 35 U.S.C. §112 rejection for claims 1-4 and 6-26 is respectfully requested.

# III. 35 U.S.C. §101

It is asserted in the Office Action that claims 1-4, 6-21, 25 and 26 are rejected under 35 U.S.C. §101. Applicant has amended the claims to overcome the 35 U.S.C. §101 rejections. Applicant notes that the claims are amended as directed to methods of treatment.

Regarding the Examiner's assertion that claims 12 and 14 are indefinite for asserting the terms "ellagic acid and its derivatives" is unclear, we respectfully disagree. We note that person skilled in the art can identify the derivatives of ellagic acid as those that keep the main structure of ellagic acid.

Regarding the terms "such as," Applicant has deleted these terms.

Accordingly, withdrawal of the 35 U.S.C. §101 rejections for claims 1-4, 6-21, 25 and 26, and the indefinite rejections for claims 12, 14, 22 and 24 are respectfully requested.

### IV. <u>35 U.S.C. §102(b)</u>

It is asserted in the Office Action that claims 1-4, 6-12, 14-20, 22-24 and 26 are rejected under 35 U.S.C. §102(b) as being anticipated by WO 95/21018 or its counterpart U.S. Patent No. 5,780,060 issued to Levy ("Levy"). Applicant respectfully disagrees.

According to MPEP §2131, "'[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' (Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). 'The identical invention must be shown in as complete detail as is contained in the ... claim.' (Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. (In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990))."

Applicant's amended claim 1 contains the limitations of "[m]ethod for activating the endogenous synthesis of Heat Shock Protein (HSP) 32 or a functional peptide fragment of such a protein, comprising the administration to a subject in need thereof of a composition containing at least one compound chosen from the group consisting of Procyanidol Oligomers (PCOs) and derivatives thereof, caffeic acid esters and derivatives thereof and mixtures of these compounds."

Applicant's amended claims 14 contains the limitations of "[d] ermatological or cosmetological method for activating the endogenous synthesis of Heat Shock Protein (HSP) 32 or a functional peptide fragment of such a protein, comprising the administration to a subject in need thereof of a composition containing at least one compound according to Claim 1, in combination with at least one component chosen from:- forskolin or any extract containing it, - tyrosine and its derivatives, with the exception of L-DOPA (or "3-hydroxy-L-tyrosine"), - ellagic acid and its derivatives or any extract containing them, - extracts of Centella asiatica, of Potentilla erecta and of Eriobotrya japonica, - soybean saponins and alfalfa saponins, - isoflavones, - vitamin C and its derivatives, - 18-β-glycyrrhetinic acid, - extracts of Azadiracta indica, - curcuminoids, with pharmaceutically and/or cosmetically acceptable excipients."

That is, Applicant's claims are directed to methods of treatment where Procyanidol Oligomers (PCOs) can activate the endogenous synthesis of Heat Shock Protein (HSP) 32.

Levy discloses cosmetic protective compositions containing microcapsules based on crosslinked plant polyphenols. Levy, however, does not teach, disclose or suggest methods for treatment where PCOs can activate the endogenous synthesis of HSP 32. In particular, Levy does not teach, disclose or suggest the limitations of "[m]ethod for activating the endogenous synthesis of Heat Shock Protein (HSP) 32 or a functional peptide fragment of such a protein, comprising the administration to a subject in need thereof of a composition containing at least one compound chosen from the group consisting of Procyanidol Oligomers (PCOs) and derivatives thereof, caffeic acid esters and derivatives thereof and mixtures of these compounds," or "[d] ermatological or cosmetological method for activating the endogenous synthesis of Heat Shock Protein (HSP) 32 or a functional peptide fragment of such a protein, comprising the administration to a subject in need thereof of a composition containing at least one compound according to Claim 1 ..."

Therefore, since <u>Levy</u> does not disclose, teach or suggest all of Applicant's amended claims 1 and 14 limitations, Applicant respectfully asserts that a *prima facie* rejection under 35 U.S.C. § 102(b) has not been adequately set forth relative to <u>Levy</u>. Thus, Applicant's amended claims 1 and 14 are not anticipated by <u>Levy</u>. Additionally, the claims that depend directly or indirectly on claims 1 and 14, namely claims 2-4, 6-12 and 26, and 15-20 and 22-24, respectively, are also not anticipated by <u>Levy</u> for the above same reason.

Accordingly, withdrawal of the 35 U.S.C. §102(b) rejection for claims 1-4, 6-12, 14-20, 22-24 and 26 is respectfully requested.

# V. 35 U.S.C. §103(a)

A. It is asserted in the Office Action that claims 13 and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over <u>Levy</u> in view of U.S. Patent No. 6,066,333 issued to Willis et al. ("<u>Willis</u>"). Applicant respectfully disagrees.

According to MPEP §2142 "[t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either

in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." (In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Further, according to MPEP §2143.03, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." "All words in a claim must be considered in judging the patentability of that claim against the prior art." (In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), emphasis added.)

Applicant has discussed claims 1 and 14, of which claims 13 and 21 depend on, respectively, above in section IV regarding <u>Levy</u>.

Willis discloses what Heat Shock Proteins (HSPs) are, and how they serve vital roles to the cell. Willis also discloses that "[I]mmune responses to HSPs have been implicated in adjuvant arthritis in the rat, pristane arthritis in the mouse, diabetes mellitus in the non-obese diabetic mouse, rheumatoid arthritis, systemic lupus, erythematosus, atherosclerossis and in tumor surveillance. Therefore, it appears that HSPs may have a parydoxical effect in pathological condition, having a cytoprotective effect on cells and tissue in stressful environments, but elliciting a detrimental immune response in some autoimmune diseases." (Willis, column 2, lines 51 - 60). Willis, however, does not teach, disclose or suggest methods for treatment where PCOs can activate the endogenous synthesis of HSP 32. Further, Willis does not teach, disclose or suggest the limitations of "[m]ethod for activating the endogenous synthesis of Heat Shock Protein (HSP) 32 or a functional peptide fragment of such a protein, comprising the administration to a subject in need thereof of a composition containing at least one compound chosen from the group consisting of Procyanidol Oligomers (PCOs) and derivatives thereof, caffeic acid esters and derivatives thereof and mixtures of these compounds," or "[d] ermatological or cosmetological method for activating the

endogenous synthesis of Heat Shock Protein (HSP) 32 or a functional peptide fragment of such a protein, comprising the administration to a subject in need thereof of a composition containing at least one compound according to Claim 1 ..."

Neither Levy, Willis, nor the combination of the two, teach, disclose or suggest all the limitations of Applicant's amended claims 1 and 14. Since neither Levy, Willis, nor the combination of the two disclose, teach or suggest all the limitations contained in Applicant's amended claims 1 and 14, as listed above, there would not be any motivation to arrive at Applicant's claimed invention. Thus, Applicant's amended claims 1 and 14 are not obvious over Levy in view of Willis since a prima facie case of obviousness has not been met under MPEP 2142. Additionally, the claims that directly or indirectly depend from Applicant's amended claims 1 and 14, namely claims 13, and 21, respectively, are also not obvious over Levy in view of Willis for the above same reason.

Accordingly, withdrawal of the 35 U.S.C. §103(a) rejection for claims 13 and 21 are respectfully requested.

B. It is asserted in the Office Action that claim 25 is rejected under 35 U.S.C. §103(a) as being unpatentable over <u>Willis</u> in view of no other prior art. Applicant respectively disagrees.

Applicant's amended claim 25 contains the limitations of "[u]se of the heat shock protein (HSP) 32 as a cosmetic product."

Willis discloses what Heat Shock Proteins (HSPs) are, and how they serve vital roles to the cell. Willis also discloses that "[I]mmune responses to HSPs have been implicated in adjuvant arthritis in the rat, pristane arthritis in the mouse, diabetes mellitus in the non-obese diabetic mouse, rheumatoid arthritis, systemic lupus, erythematosus, atherosclerossis and in tumor surveillance. Therefore, it appears that HSPs may have a parydoxical effect in pathological condition, having a cytoprotective effect on cells and tissue in stressful environments, but elliciting a detrimental immune

response in some autoimmune diseases." (Willis, column 2, lines 51 - 60). Nowhere in Willis, however, is it taught, disclosed or suggested to use HSP32 as a cosmetic product.

Further, the point in time that is critical for an obviousness determination is at the time the invention. "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Obviousness cannot be established by hindsight combination to produce the claimed invention. (In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed.Cir.1991)). It is the prior art itself, and not the applicant's achievement, that must establish the obviousness of the combination. Applicant submits that without the disclosure in Applicant's specification, no other prior art reference taught, suggested, or disclosed to use HSP32 as a cosmetic product.

Since <u>Willis</u> does not disclose, teach or suggest all the limitations contained in Applicant's amended claim 25, as listed above, there would not be any motivation to arrive at Applicant's claimed invention. Thus, Applicant's amended claim 25 is not obvious over <u>Willis</u> in view of <u>no other prior art</u> since a *prima facie* case of obviousness has not been met under MPEP 2142.

Accordingly, withdrawal of the 35 U.S.C. §103(a) rejection for claim 25 is respectfully requested.

#### **CONCLUSION**

In view of the foregoing, it is submitted that claims 1-35 patentably define the subject invention over the cited references of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes a telephone conference would be useful in moving the case forward, he is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly, extension of time fees.

### PETITION FOR EXTENSION OF TIME

Per 37 C.F.R. 1.136(a) and in connection with the Office Action mailed on Tuesday, June 17, 2003, Applicant respectfully petitions the Commissioner for a two (2) month extension of time, extending the period for response to Tuesday, November 4, 2003. The Commissioner is hereby authorized to charge payment to Deposit Account No. 02-2666 in the amount of \$420.00 to cover the petition filing fee for a 37 C.F.R. 1.17(a)(2) large entity. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR, & ZAFMAN LLP

Dated: November 4, 2003

Steven Laut, Reg. No. 47,736

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